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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,512	12/12/2003	Salman Al-Mahmood	1414-03	6845

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IP GROUP OF DLA PIPER US LLP
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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,512	AL-MAHMOOD, SALMAN	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 19, 20, 26, and 27 drawn to compositions comprising as an active agent a nucleic acid molecule of the gene coding for IRS-1 and fragments thereof, classified in class 536, subclass 23.1.

II. Claims 1-6, 19, 20, 26, and 27 drawn to compositions comprising as an active agent a nucleic acid molecule which inhibits the expression of the gene coding for protein IRS-1 and fragments thereof, classified in class 536, subclass 24.5. Election of this group requires the further election of a single nucleotide sequence from the group consisting of SEQ ID NOS: 2-23 and 28 for reasons discussed below. This is not a species election.

III. Claims 7-16, 21-23 drawn to methods of inhibiting angiogenesis comprising administering a molecule which inhibits the expression of the gene coding for IRS-1, classified in class 514, subclass 44. Election of this group requires the further election of a single nucleotide sequence from the group consisting of SEQ ID NOS: 2-23 and 28 for reasons discussed below. This is not a species election. Election of this group also requires a further election of species of a specific disease type as recited in claims 12 and 23.

IV. Claims 17, 18, 24, and 25, drawn to methods of diagnosing pathologies linked to angiogenesis comprising contacting a composition comprising as an active agent a

nucleic acid molecule of the gene coding for IRS-1 and fragments thereof, classified in class 435, subclass 6. Election of this group also requires a further election of species of a specific disease type as recited in claims 18 and 25.

V. Claims 17, 18, 24, and 25, drawn to methods of diagnosing pathologies linked to angiogenesis comprising contacting a composition comprising as an active agent a molecule which inhibits the expression of a nucleic acid molecule of a gene coding for IRS-1 and fragments thereof, classified in class 435, subclass 6. Election of this group also requires a further election of species of a specific disease type as recited in claims 18 and 25.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. Inventions IV and V are directed to related methods. However, I and II are considered distinct, and IV and V are also considered distinct, for the same reasons. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not capable of use together, since the inventions of Groups I and IV are directed to activation of IRS-1 activity, while the inventions of Group II and V are directed to inhibition of IRS-1 activity. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Because these inventions are independent or distinct for the reasons given above and

there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The method of Group III is related to the methods of Groups IV and V. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because the invention of Group III requires treatment of angiongenesis, while that of Groups IV and V do not require treatment, but require comparing diagnosing pathologies comprising the step of determining IRS-1 inhibition before and after active agent administration. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the IRS-1 encoding RNA cannot be used in the process of inhibiting IRS-1. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is

not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The invention of Group II is related to that of Group III-V as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products as claimed can be used as probes to detect the presence of the IRS-1 mRNA. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: rheumatoid arthritis, Crohn's disease, atherosclerosis, hyperstimulation of the ovary, psoriasis, endometritis associated with neovascularization, restenosis due to balloon angioplasty, tissue superproduction due to cicatrization, peripheral vascular disease, hypertension, vascular inflammation, Raynaud's disease and Raynaud's phenomena, aneurysm, arterial restenosis, thrombophlebitis, lymphangitis, lymphedema, tissue cicatrization and repair, ischemia, angina, myocardial infarction, chronic heart disease, congestive heart failure, age-related macular degeneration or osteoporosis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Sequence Restriction

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences listed in the Groups above are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

The instant invention contains claims drawn to specific antisense SEQ ID NOS, which are targeted to and modulates the expression of IRS-1. Although the antisense sequences claimed each target and modulate expression of the same gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of

IRS-1, and each antisense, upon binding to IRS-1, functionally modulates (increases or decreases) the expression of the gene and to varying degree. Furthermore, a search of more than one (1) of the antisense sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, should applicants elect a Group containing multiple antisense sequences as defined above, applicants are further required to elect one (1) antisense sequence from that Group.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER